

REMARKS

Amendments to the Claims

Claim 1 has now been amended to specify that the pH sensor is mounted on a catheter. Basis for this amendment can be found in original claim 4.

Claim 1 has also been amended to specify that the pH sensor consists of a single probe. Basis for this amendment can be found in page 10, lines 20 to 29 of the application as filed, which discloses that the catheter 1 has a pH sensor probe 5 (i.e. a single probe) mounted thereon. Further basis can be found on page 12, line 9, which begins "*the* pH probe and cable...." (emphasis added). Hence this application clearly discloses a catheter with a *single* pH probe and not a plurality of pH probes. Further basis for this amendment can be found in Fig 1, which shows the single pH sensor probe 5 on the catheter 1. All of the examples of the invention disclosed in the application use the single pH probe embodiment.

Minor amendments have been made to claims 5 and 7 (see below).

No new matter has been added.

Objection to claim 7 due to informalities

The Examiner objected that the comma in "communicating with, the fracture site" was a typographical error. This was not the case. The entire phrase read: "the cannula is inserted into the muscle adjacent to, but not communicating with, the fracture site." The comma indicated to the reader that the cannula is adjacent to the fracture site, "the fracture site" being after the clause "but not communicating with". Without the comma, the clause "but not communicating with" is incorrect, and there is no indication what the muscle is adjacent to.

However, in consequence of the Examiner's objection, claim 7 has been amended so that its meaning is more explicit, and without the use of the comma to which the Examiner objected.

Rejection of claims 5 and 7 under 35 USC 112

The Examiner objected that "the muscle" in claim 5 lacked sufficient antecedent basis. "The muscle" has been amended to "a muscle", to correct this.

The Examiner objected that claim 7 is indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention. Claim 7 has now been reworded, with the aim of increasing its clarity, so the Examiner's objection is now moot.

Rejection of claims 1-3, 8, 9 and 11 under 35 USC 102(b)

The Examiner expressed the view that claims 1-3, 8, 9 and 11 were anticipated by US 5,766,432 (Dunn).

Claim 1 has now been amended to specify that the pH sensor consists of a single probe mounted on a catheter.

In contrast, Dunn does not teach a method of diagnosing a pathological condition using a pH sensor that consists of a single probe mounted on a catheter. Instead, Dunn teaches that multiple pairs of electrodes are required (see column 6, lines 13 to 23, which describes five separate reference electrodes 52a-e, in addition to a pH measuring electrode 54).

Hence, amended claim 1 is novel over Dunn.

Claim Rejections - 35 USC 103

The Examiner expressed the view that claims 4-7 were unpatentable over Dunn in view of US 6,567,679 (Khuri).

However, claim 1 has now been amended to specify that the pH sensor consists of a single probe.

Throughout the specification, Dunn emphasizes the importance of using multiple reference electrodes in addition to a pH-measuring electrode. Dunn teaches that conventional pH-measuring devices are impaired by time-dependent drifts in the electric potential (column 1, lines 44-51). The purpose of Dunn is to provide a method and device for measuring pH and correcting for electrode drift (column 1, lines 53-54). Drift is when an electrode starts to provide readings which are no longer reliable - the electrode has drifted away from the accurate readings it used to provide. In Dunn, correction for drift is achieved by using a pH-measuring electrode in combination with a plurality of reference electrodes. Together, each reference electrode and the pH-measuring electrode form a separate "electrode pair", which measures a pH value (column 1, line 53 to column 2, line 7). Each pair of electrodes is continuously monitored. It is obvious when one electrode drifts, because it will start to provide readings which are significantly different from the other electrode pairs (see Fig 2).

The person of ordinary skill reading Dunn would never wish to substitute Dunn's plurality of electrodes for a single probe, because Dunn teaches that having a plurality of electrodes is essential for correction of electrode drift. If Dunn's electrodes were substituted for a single probe, Dunn would be unable to correct for electrode drift.

Hence, the person of ordinary skill is actively discouraged from any change to a single probe system, because it would be impossible to achieve Dunn's objective of correction for electrode drift, without any further probes with which to make a comparison.

Khuri is concerned with monitoring pH in a heart during cardiac surgery. As explained in column 1, lines 22 to 30, during the cardiac surgery, the aorta is clamped, which deprives the myocardium of its blood and nutrient supply. This is done because it is not easy to perform such surgery on a beating heart. Stopping the blood supply will cause acidosis/ischemia, so it is not desirable to keep the blood supply cut off for too long. On the other hand, the surgeon wants to have as much time as possible to operate, without damaging the patient. Therefore, Khuri describes how the pH of the myocardium is monitored to determine the degree of tissue acidosis and thus the onset of myocardial ischemia. Hence, as described on column 1, lines 57 to 59, the safe period of oxygen deprivation can be extended.

Therefore, in Khuri's method, the cause of this acute ischemia is the surgery itself. This ischemia did not exist before the surgery, but was instead caused by the surgical act of clamping the aorta, cutting off the blood supply. Hence, the ischemia in this example is not caused by a disease or injury, and is therefore not a pathological condition.

Amended claim 1 is novel over Khuri, because Khuri does not disclose:

- a) a method of diagnosing a pathological condition of a patient's body tissue; or
- b) using a pH measurement to diagnose the pathological condition.

Amended claim 1 is directed to a completely different technical field than that of Khuri - of diagnosing a pathological condition, rather than the field of keeping a heart healthy during surgery. One such pathological condition is compartment syndrome, which is described on page 2, line 11 to page 3, line 8 of the application as filed. To monitor compartment syndrome, it is known to use pressure monitoring (page 3, lines 10-13). The invention uses a new monitoring method - pH monitoring - instead of the known pressure monitoring method. This is not merely an obvious modification, because compartment syndrome is defined as "a condition in which increased pressure within a limited space compromises the circulation and function of tissues in that space" (see page 2, lines 16 to 19 of the application as filed). Hence, when trying to identify a condition defined by increased pressure, it may be obvious to monitor pressure. However, it is not at all obvious to monitor an entirely different parameter, such as pH, or to realise that pH monitoring may give more reliable results.

A person of ordinary skill who is looking to improve a method of diagnosing a pathological condition such as acute compartment syndrome would not turn to Khuri, which is in the different technical field of keeping a heart healthy during surgery, whilst a blood supply is deliberately cut off.

Even if the person of ordinary skill did turn to Khuri, he would learn that if you are wishing to prevent tissue acidosis during a surgical operation, pH can be monitored. However, this does not automatically lead him, without any exercise of inventive activity, to decide to use pH monitoring in the completely different field of diagnosis of pathological conditions, particularly when some such conditions, e.g. compartment syndrome, are defined in terms of an excess of

pressure, and not pH. Thus, monitoring of pH in such conditions is actually counter-intuitive, when directly monitoring the parameter which actually defines the condition (pressure) is already known.

In the office action, the Examiner cited column 2, lines 5-18 of Khuri, which disclose that Khuri's electrode can be delivered by a catheter. However, this is irrelevant to the present invention because Khuri does not teach a method of diagnosing a pathological condition of a patient's body tissue.

It is therefore apparent that Dunn and Khuri concern two quite different medical technologies, which it is not appropriate or suitable to combine.

First, Dunn uses a plurality of electrodes for the purpose of determining electrode drift, especially for usage over time periods longer than 24 hours (see column 1, lines 48 to 50). Secondly, we have Khuri, which discloses a device to be used over the much shorter time-scale of heart surgery, and which is only concerned with man-made ischemias, not pathological conditions.

The person of ordinary skill would not seek to combine aspects of these two different methods and devices of Dunn and Khuri, because he would see that these disclosures are incompatible. Combining these two disclosures is a hindsight analysis, performed with foreknowledge of the present invention, and is not what a person of ordinary skill would have found obvious at the time the present invention was made.

Starting from Dunn, there is no motivation to redesign Dunn's apparatus to use a pH sensor comprising a single probe, because Dunn's equipment would no longer be fit for Dunn's purpose of measuring electrode drift over long time scales. The person of ordinary skill would find Khuri's method of measuring induced ischemia during the short time scale of heart surgery to be irrelevant to Dunn's method.

Therefore, amended claim 1 is non-obvious over Dunn, even in view of Khuri, and the Examiner's objections to claims 4-7 as being unpatentable over Dunn in view of US 6,567,679 (Khuri) are now moot.

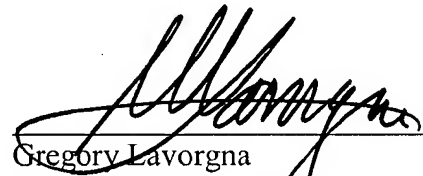
Claims 2, 3, 5 to 9 and 11

Claims 2, 3, 5 to 9 and 11 are all dependent on claim 1, and thus are also novel and non-obvious, at least by virtue of this dependency.

Request for Allowance

It is believed that the claims, as amended, are allowable and notification to this effect is earnestly solicited. Should the Examiner have any questions or comments regarding Applicants' amendments or response, he is asked to contact Applicants' undersigned representative at (215) 988.3303. Please direct all correspondence to the below-listed address. If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573.

Respectfully submitted,



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